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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,797	09/29/2005	Rajesh Jain	U 015961-3	4219

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EXAMINER

MCCORMICK, MELENIE LEE

ART UNIT PAPER NUMBER

1655

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/551,797	Applicant(s) JAIN ET AL.	
	Examiner Melenie McCormick	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-67 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-67 are presented for examination on the merits.

Claim Objections

Claims 1, 32, 37, and 40 are objected to because of the following informalities:
In claim 1, the word "of" in lines 3 and 8 is unnecessary and confusing. In claim 1, the word "comprise" in line 8 is not grammatically correct. It is suggested that "comprise" be changed to "comprises". In claim 32, a space is missing between the word "claim" and the number "31" in line 1. In claim 37, the word "to" after the number "34" line 2 is unnecessary and confusing. In claim 40, a space is missing between the word "between" and the number "0". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 67 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 67 provides for the use of an extract of the plant *Euphorbia prostrata*, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1 and 34, the phrase "extract of the plant *Euphorbia prostrata* containing flavonoids and phenolic compounds" in lines 3-4 is vague and indefinite because it is unclear if these flavonoids and phenolic compounds are added to the extract or if they are naturally found within the extract. Regarding claims 1, 6, 9, 17, 20, 25, 66, and 67, the phrase "and the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "and the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). Regarding claims 66 and 67, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Double Patenting

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-33 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 5,858,371.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the reference claims and the instant claims teach a pharmaceutical composition comprising an extract of *Euphorbia prostrata* for the treatment of anorectal or colonic diseases.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al (US 5,858,371).

A pharmaceutical composition for the treatment of anorectal or colonic diseases and a method of making and using the composition is claimed.

Singh et al. beneficially teach a composition for the treatment of anorectal and colonic diseases (see e.g. col 1, lines 6-8). Singh et al. further beneficially teach that the pharmaceutical composition contains an extract of the plant *Euphorbia prostrata*, a pharmaceutically acceptable carrier, and the flavonoids apigenin-7-glycoside, luteolin-7-glycoside, luteolin, and quercetin (see e.g. claim 1). Singh et al. further beneficially teach that the composition additionally contains tannins, therapeutic agents, including the particular therapeutic agents instantly claimed (most of which are in the particular amounts as instantly claimed) (see e.g. claims 5-30). Singh et al. also beneficially teach that the composition may be in the form of a cream, ointment, solution, spray, foam, suppository, medicated pad, bandage, powder, suspension, film, flake, oral hard gelatin capsule, soft gelatin capsule, coated and uncoated tablet, sustained (modified) release dosage form, liquid, lozenge, wafer or caplet as instantly claimed (see e.g. claim 31). Singh et al. also disclose a method of making a pharmaceutical composition (see e.g. col 10, lines 53-54). Singh et al. beneficially teach that *Euphorbia prostrata* was dried, ground into a coarse powder, extracted with ethyl alcohol (a polar solvent), which was repeated 5 times, concentrated under vacuum (which has the same concentrating effect as distillation), extracted with 5-10 volumes a non-polar solvent (which would

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intrinsically wash the extract), and dried (see e.g. col 10, line 55-col 11, line 11).

Because this extract was prepared in the manner instantly claimed, it would have intrinsically contained the flavonoids and phenolic compounds instantly claimed, but not expressly taught by Singh et al. (apigenin, ellagic acid, and gallic acid). It is further disclosed by Singh et al. that the composition was administered to patients with complaints of hemorrhoids and fissure in oral and topical dosage forms, which reads on the method of treating anorectal or colonic diseases such as hemorrhoids and fissure instantly claimed (see e.g. col 13, lines 15-21).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a composition for the treatment of anorectal or colonic diseases comprising an extract of *Euphorbia prostrata* and the therapeutic agents instantly claimed based upon the beneficial teaching of Singh et al. of a composition which comprises these components. One of ordinary skill in the art at the time the claimed invention was made would have been motivated to prepare an extract for use in a composition and use the composition in the manner instantly claimed, especially because Singh et al. beneficially teach that the extract is made and the composition used in this manner and for the same purpose. The adjustment of particular conventional working conditions (e.g. the particular result effective percentages by weight of the individual components or repetition of particular method steps) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER R. TATE
PRIMARY EXAMINER